

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

To:
THOMAS J. KRUMENACHER
RYAN KROMHOLZ & MANION, S.C.
P.O. BOX 26618
MILWAUKEE, WI 53226

Date of mailing
(day/month/year)

16 APR 2009

Applicant's or agent's file reference
20759-PCT

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/US 08/13650

International filing date
(day/month/year) 12 December 2008 (12.12.2008)

Applicant MIRAMAR LABS, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 8270

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

APR 20 2009

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

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NOTIFICATION OF TRANSMITTAL OF
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THE WRITTEN OPINION OF THE INTERNATIONAL
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PCT/US 08/13650

International filing date
(day/month/year) 12 December 2008 (12.12.2008)

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Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 8270

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

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☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

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The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|--|--|--|
| Applicant's or agent's file reference 20759-PCT | FOR FURTHER ACTION | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |
| International application No. PCT/US 08/13650 | International filing date (<i>day/month/year</i>) 12 December 2008 (12.12.2008) | (Earliest) Priority Date (<i>day/month/year</i>) 22 October 2008 (22.10.2008) |
| Applicant MIRAMAR LABS, INC. | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

☐ as suggested by the applicant.

☒ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/13650

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 8
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claim 8 is incomplete.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 and 9-35, drawn to a disposable, vacuum driven, multi-chambered tissue securing apparatus for medical treatment
 Group II: Claims 36-59, drawn towards an energy transmission apparatus for medical treatment
 Group III: Claims 60-64, drawn towards methods for applying energy to waveguides
 Group IV: Claims 65-66, drawn towards a patient support apparatus
 Group V: Claims 67-69, drawn towards a treatment template

The inventions listed as Groups I - V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack a novel technical feature.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
1-7 and 9-59

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/13650

| A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61N 5/02 (2009.01) USPC - 607/101 According to International Patent Classification (IPC) or to both national classification and IPC | | |
|--|--|--|
| B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) USPC: 607/101 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC: 607/101, 154, 109, 50, 115, 145, 148, 149, 150 See Search Terms Below Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) pubWEST(PGPB,USPT,EPAB,JPAB); Google Search Terms Used: microwave, vacuum, suction, filter, barrier, film, cooling, coolant, disposable, compliant, flexible, tissue, housing, chamber, grasp\$3, grab\$3 | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | US 2004/0049251 A1 (KNOWLTON) 11 March 2004 (11.03.2004) entire document, especially para [0092]-[0094], [0123], [0140]-[0142], [0162], [0173], [0190]-[0191], [0220], [0222]-[0223], [0233], [0270], [0281], [0302]-[0303], fig 2C, 4, 72 | 1-7 and 9-17 |
| Y | | 18-59 |
| Y | 2007/0179482 A1 (ANDERSON) 02 August 2007 (02.08.2007) para [0017], [0073]-[0074], [0129], fig 3 | 18-29 and 35 |
| Y | US 4,140,130 A (STORM) 20 February 1979 (20.02.1979) (col 6, ln 4-7, col 6, ln 18-19, col 6, ln 45-48, fig 1, 3, 4) | 30-59 |
| Y | US 2004/0243200 A1 (TURNER et al) 02 December 2004 (02.12.2004) para [0040] | 50-54 and 59 |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> | | |
| * Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family | | |
| Date of the actual completion of the international search 01 April 2009 (01.04.2009) | | Date of mailing of the international search report 16 APR 2009 |
| Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201 | | Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774 |

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

To: THOMAS J. KRUMENACHER
RYAN KROMHOLZ & MANION, S.C.
P.O. BOX 26618
MILWAUKEE, WI 53226

Date of mailing
(day/month/year) **16 APR 2009**

Applicant's or agent's file reference
20759-PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US 08/13650

International filing date (day/month/year)

12 December 2008 (12.12.2008)

Priority date (day/month/year)

22 October 2008 (22.10.2008)

International Patent Classification (IPC) or both national classification and IPC

IPC(8) - A61N 5/02 (2009.01)

USPC - 607/101

Applicant **MIRAMAR LABS, INC.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☐ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. **571-273-3201**

Date of completion of this opinion

01 April 2009 (01.04.2009)

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 08/13650

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 08/13650

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. ⁸ _____

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. ⁸ _____ are so unclear that no meaningful opinion could be formed (*specify*):

Claim 8 is incomplete

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. ⁸ _____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 08/13650

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☒ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

☐ complied with

☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 and 9-35, drawn to a disposable, vacuum driven, multi-chambered tissue securing apparatus for medical treatment

Group II: Claims 36-59, drawn towards an energy transmission apparatus for medical treatment

Group III: Claims 60-64, drawn towards methods for applying energy to waveguides

Group IV: Claims 65-66, drawn towards a patient support apparatus

Group V: Claims 67-69, drawn towards a treatment template

The inventions listed as Groups I - V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack a novel technical feature.

The special technical feature of Group I is a vacuum driven, tissue securement apparatus, whereas the technical feature of Group II is an energy transmission apparatus for medical treatment. Group III provides a special technical feature of methods for applying energy to waveguides, while Group IV provides a special technical feature of a patient support apparatus. Finally, Group V provides a special technical feature of a treatment template. The special feature of Group II (energy application), is obvious over prior art, as any energy application method could be used with the invention of Group I, while Groups III provides an alternate method for application of energy using any energy application device, and not specifically the device of Group II. Groups IV-V do not have special technical features shared by the other group, nor do they correspond to a special technical feature in the other group. Accordingly, unity of invention is lacking under PCT Rule 13.1.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☐ all parts

☒ the parts relating to claims Nos. 1-7, 9-59

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 08/13650

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|----------------------|-----|
| Novelty (N) | Claims | 4, 5, 9-13 and 16-59 | YES |
| | Claims | 1-3, 6, 7, 14 and 15 | NO |
| Inventive step (IS) | Claims | None | YES |
| | Claims | 1-7 and 9-59 | NO |
| Industrial applicability (IA) | Claims | 1-7 and 9-59 | YES |
| | Claims | None | NO |

2. Citations and explanations:

Claims 1-3, 6, 7, 14 and 15 lack novelty under PCT Article 33(2) as being anticipated by US 2004/0049251 A1 (Knowlton).

Regarding claim 1, Knowlton discloses disposable medical apparatus comprising:

a tissue chamber positioned at a distal end of said disposable member (para [0092], [0098], [0162], part 12, fig 4);
an applicator chamber positioned at a proximal end of said disposable member (para [0092], [0097], [0162], fig 2C);
a tissue bio-barrier separating said tissue chamber and said applicator interface (para [0142]); and
a vacuum circuit connecting said tissue chamber and said applicator chamber (para [0190]-[0191]).

Regarding claim 2, Knowlton further discloses a disposable medical apparatus according to Claim 1 wherein said tissue chamber comprises:

a tissue interface surface, said tissue interface surface comprising:
vacuum channels surrounding said tissue bio-barrier (para [0196]);
vacuum ports in flow communication with said vacuum channels and said vacuum circuit (para [0162]); and chamber walls surrounding said tissue chamber (fig 4).

Regarding claim 3, Knowlton further discloses a disposable medical apparatus according to Claim 2 wherein said chamber walls further include a compliant member (para [0173]).

Regarding claim 6, Knowlton further discloses a disposable medical apparatus according to Claim 2 wherein said chamber walls further include a lubricant coating at least a portion of said chamber walls (para [0123]).

Regarding claim 7, Knowlton further discloses a disposable medical apparatus according to Claim 6 wherein said lubricant is selected from the group consisting of: silicone oil, Teflon, paralene or other suitable coating material to ease acquisition of tissue (para [0123]).

Regarding claim 14, Knowlton teaches a disposable medical apparatus according to Claim 1, wherein said tissue bio-barrier is flexible (para [0097], [0142], fig 2C).

Regarding claim 15, Knowlton teaches a disposable medical apparatus according to Claim 14, wherein said tissue bio-barrier is a film (para [0142]).

Claims 4, 5, 9-13, 16 and 17 lack an inventive step under PCT Article 33(3) as being obvious over Knowlton.

Regarding claim 4, Knowlton discloses a disposable medical apparatus according to Claim 3, but does not specifically teach wherein said compliant member has a height of between approximately .15 inches and approximately .25 inches. With routine experimentation, it would have been obvious to one of ordinary skill in the art that the compliant member could have a variety of heights based on the elasticity of the skin and the size of the treatment area, including the range of .15-.25 inches.

Regarding claim 5, Knowlton discloses a disposable medical apparatus according to Claim 3, but does not specifically teach wherein said compliant member has a height of approximately .25 inches. With routine experimentation, it would have been obvious to one of ordinary skill in the art that the compliant member could have a height of .25 inches based on the elasticity of the skin and the size of the treatment area.

Regarding claim 9, Knowlton teaches a disposable medical apparatus according to Claim 1 wherein said applicator chamber comprises: an applicator interface surface wherein said applicator interface surface surrounds said tissue bio-barrier (para [0142]); applicator interface walls surrounding said applicator interface surface (para [0092], fig 2C); but does not teach a vacuum seal at a proximal end of said applicator chamber, said vacuum seal being positioned to hermetically seal said applicator chamber when an applicator is positioned in said applicator chamber. However, it would have been obvious to one of ordinary skill in the art that the applicator chamber could be hermetically sealed in order to prevent biological contamination and possible patient infection.

-----Continued on Supplemental Page-----

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 08/13650

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 8 is incomplete and could not be examined.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 08/13650

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V, Part 2:

Regarding claim 10, Claim 9 is obvious as above. Knowlton teaches wherein said applicator chamber has a depth sufficient to receive and engage an applicator such that a distal end of said applicator contacts said tissue bio-barrier, creating an interference fit between said distal end of said applicator and said tissue bio-barrier (para [0092]).

Regarding claim 11, Claim 10 is obvious as above. Knowlton does not specifically teach wherein said applicator chamber has a depth sufficient to ensure that an applicator positioned in said applicator chamber moves said bio-barrier between approximately .001 inches and approximately .030 inches into said tissue chamber. With routine experimentation, it would have been obvious to one of ordinary skill in the art that the applicator chamber could be designed in order to move the bio-barrier .001-.030 inches into the tissue chamber in order for the applicator to engage tissue in said tissue chamber.

Regarding claim 12, Claim 10 is obvious as above. Knowlton does not specifically teach wherein said applicator chamber has a depth sufficient to ensure that an applicator positioned in said applicator chamber moves said bio-barrier approximately .010 inches into said tissue chamber. With routine experimentation, it would have been obvious to one of ordinary skill in the art that the applicator chamber could be designed in order to move the bio-barrier .010 inches into the tissue chamber in order for the applicator to engage tissue in said tissue chamber.

Regarding claim 13, Claim 9 is obvious as above. Knowlton teaches wherein said applicator chamber has a depth sufficient to receive and engage an applicator such that a distal end of said applicator contacts said tissue bio-barrier, creating an interference fit between said distal end of said applicator and said tissue bio-barrier when tissue is positioned in said tissue chamber (para [0092], [0142]).

Regarding claim 16, Knowlton discloses a disposable medical apparatus according to Claim 15, but does not specifically teach wherein said tissue bio-barrier has a thickness of between .0001 inches and approximately .030 inches. However, with routine experimentation, it would have been obvious to one of ordinary skill in the art that the bio-barrier could have a range of thicknesses dependent on the size of the housing and amount of vacuum pressure and amount of microwaves passing through the barrier.

Regarding claim 17, Knowlton discloses a disposable medical apparatus according to Claim 15, but does not teach wherein said tissue bio-barrier has a thickness of approximately .0005 inches. However, with routine experimentation, it would have been obvious to one of ordinary skill in the art that the bio-barrier could have a thickness of .0005 inches in order to be lightweight and compact, yet prevent materials from passing through the barrier.

Claims 18-29 lack an inventive step under PCT Article 33(3) as being obvious over Knowlton in light of US 2007/0179482 A1 (Anderson).

Regarding claim 18, Knowlton further teaches a disposable medical apparatus according to claim 1 wherein said vacuum circuit comprises:
a main vacuum channel (para [0191]),
vacuum ports in flow communication with both said main vacuum channel and said tissue chamber (para [0191]), but does not teach said main vacuum passage being in flow communication with said applicator chamber. However, Anderson teaches said main vacuum passage being in flow communication with said applicator chamber (para [0129]). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Anderson because doing so maintains the bio-barrier at a normalized pressure relative to prevent tearing or stretching of the bio-barrier due to the vacuum pressure.

Regarding claim 19, Claim 18 is obvious as above. Anderson teaches wherein said vacuum circuit further comprises: a vacuum connector in flow communication with said main vacuum channel (para [0073]-[0074], fig 3);
an applicator bio-barrier positioned between said main vacuum channel and said applicator chamber (para [0073]-[0074], fig 3). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Anderson because doing so provides a means for the device to hold tissue.

Regarding claim 20, Claim 19 is obvious as above. Knowlton does not specifically teach wherein said applicator bio-barrier is positioned on a first side of said disposable medical apparatus and said vacuum connector is positioned on a second side of said disposable medical apparatus. However, with routine experimentation, it would have been obvious to one of ordinary skill in the art that the bio-barrier and vacuum connector could be positioned in various places on the device in order to provide a compact design.

Regarding claim 21, Claim 20 is obvious as above. Neither Knowlton nor Anderson specifically teach wherein said main vacuum channel includes a tortuous path between said vacuum connector and said applicator bio-barrier. However, it would have been obvious to one of ordinary skill in the art that a tortuous path to reduce moisture transmission.

Regarding claim 22, Claim 21 is obvious as above. Anderson does not specifically teach wherein said main vacuum channel further comprises vacuum baffles positioned adjacent said applicator bio-barrier. However, Anderson does teach the use of valves in the vacuum channel to control pressure (para [0017]). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Anderson because doing so allows for more precise control of the pressure applied to the chambers.

Regarding claim 23, Claim 22 is obvious as above. Neither Knowlton nor Anderson teach wherein said vacuum ports contact said main vacuum channel between said vacuum connector and said vacuum baffles. However, with routine experimentation, it would have been obvious to one of ordinary skill in the art that the vacuum ports could be positioned in a number of places relative to the vacuum connector and vacuum baffles, including between the baffles and the connector because doing so requires only one vacuum connector to feed all of the ports and corresponding baffles.

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Regarding claim 24, Knowlton teaches a method of balancing vacuum pressure in a medical treatment device, wherein said medical treatment device comprises an applicator and a disposable (para [0092], [0162]), said disposable comprising a tissue chamber (para [0092], [0098], [0162], part 12, fig 4) and an applicator chamber separated by a flexible tissue bio-barrier (para [0097], [0142], fig 2C), said method comprising the steps of:
positioning an applicator in said applicator chamber such that said applicator seals an applicator chamber opening (para [0092]);
positioning tissue adjacent said tissue chamber such that said tissue at least partially seals a tissue chamber opening (para [0190]-[0191]);
drawing air from said tissue chamber (para [0191]), but does not teach drawing air from said applicator chamber. However, Anderson teaches drawing air from the applicator chamber (para [0129]). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Anderson because doing so maintains the bio-barrier at a normalized pressure relative to prevent tearing or stretching of the bio-barrier due to the vacuum pressure.

Regarding claim 25, Claim 24 is obvious as above. Knowlton further teaches said method further comprising the step of: positioning said applicator in said applicator chamber such that a distal end of said applicator forms an interference fit with said tissue bio-barrier (para [0092]).

Regarding claim 26, Claim 25 is obvious as above. Neither Knowlton nor Anderson teach positioning said applicator in said applicator chamber such that a distal end of said applicator stretches said tissue bio-barrier into said tissue chamber. However, Knowlton teaches a flexible barrier (para [0097], [0142], fig 2C). It would have been obvious to one of ordinary skill in the art that the flexible barrier could be stretched by the applicator to ensure that the barrier is taught and lies flat on the applicator surface prior to applying a vacuum to provide a consistently flat surface for tissue engagement.

Regarding claim 27, Claim 26 is obvious as above. Neither Knowlton nor Anderson specifically teach stretching said tissue bio-barrier into said tissue chamber a distance of between approximately .001 inches and approximately .030 inches. With routine experimentation, it would have been obvious to one of ordinary skill in the art that the applicator chamber could be designed in order to move the bio-barrier .001-.030 inches into the tissue chamber in order for the applicator to engage tissue in said tissue chamber.

Regarding claim 28, Claim 26 is obvious as above. Neither Knowlton nor Anderson specifically teach stretching said tissue bio-barrier into said tissue chamber a distance of approximately .010 inches. With routine experimentation, it would have been obvious to one of ordinary skill in the art that the applicator chamber could be designed in order to move the bio-barrier .010 inches into the tissue chamber in order for the applicator to engage tissue in said tissue chamber.

Regarding claim 29, Claim 24 is obvious as above. Anderson further teaches drawing air from an applicator chamber includes the step of drawing air through a bio-barrier (para [0074], [0129]). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Anderson because doing so maintains the bio-barrier at a normalized pressure relative to prevent tearing or stretching of the bio-barrier due to the vacuum pressure.

Claims 30-34, 36-49 and 55-58 lack an inventive step under PCT Article 33(3) as being obvious over Knowlton in light of US 4,140,130 A (Storm).

Regarding claim 30, Knowlton teaches a method of creating a lesion in a region of skin tissue below a first region of the dermis using a medical treatment device, wherein said medical treatment device comprises an applicator (para [0092]), said applicator comprising a disposable, said disposable comprising a tissue chamber (para [0092], [0098], [0162], part 12, fig 4) and an applicator chamber separated by a flexible tissue bio-barrier (para [0097], [0142], fig 2C), said method comprising the steps of:
positioning said applicator in said applicator chamber such that said applicator seals an applicator chamber opening (para [0092]);
positioning said skin tissue adjacent said tissue chamber such that said tissue at least partially seals a tissue chamber opening (para [0190]-[0191]);
drawing air from said tissue chamber (para [0190]-[0191]);
drawing air from said applicator chamber to pull said tissue into said applicator chamber (para [0190]-[0191]);
transmitting electromagnetic energy through said tissue bio-barrier (para [0220]), but does not teach a cooling plate. However, Storm teaches a cooling plate (col 6, ln 4 -7, col 6, ln 18-19, col 6, ln 45-48, fig 1, 3, 4). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Storm because the cooling system prevents burns to a patient's skin.

Regarding claim 31, Claim 30 is obvious as above. Knowlton teaches said method further comprising the step of: positioning said applicator in said applicator chamber such that a distal end of said applicator forms an interference fit with said tissue bio-barrier (para [0092]).

Regarding claim 32, Claim 31 is obvious as above. Neither Knowlton nor Storm specifically teach the step of positioning said applicator in said applicator chamber such that a distal end of said applicator stretches said tissue bio-barrier into said tissue chamber. However, Knowlton does teach an applicator that fits directly into the disposable housing (para [0092]) and that use of a film between the applicator and the housing (para [0142]). It would have been obvious to one of ordinary skill in the art that the barrier could be stretched in order for the applicator and barrier to protrude into the housing and contact a patient's skin.

Regarding claim 33, Claim 32 is obvious as above. Neither Knowlton nor Storm teach the step of stretching said tissue bio-barrier into said tissue chamber a distance of between approximately .001 inches and approximately .030 inches. With routine experimentation, it would have been obvious to one of ordinary skill in the art that the applicator chamber could be designed in order to move the bio-barrier .001-.030 inches into the tissue chamber in order for the applicator to engage tissue in said tissue chamber.

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Regarding claim 34, Claim 32 is obvious as above. Neither Knowlton nor Storm teach the step of stretching said tissue bio-barrier into said tissue chamber a distance of approximately .010 inches. With routine experimentation, it would have been obvious to one of ordinary skill in the art that the applicator chamber could be designed in order to move the bio-barrier .010 inches into the tissue chamber in order for the applicator to engage tissue in said tissue chamber.

Regarding claim 36, Knowlton teaches an energy transmission applicator comprising:
a disposable interface at a distal end of said applicator, said disposable interface comprising a disposable engagement mechanism (para [0162]);

an antenna structure including at least one antenna aperture arranged to transmit energy through said distal end of said applicator (para [0092]), and a cooling circuit, wherein at least a portion of said cooling circuit is positioned between said antenna and said distal end of said applicator (para [0140]) but does not teach a cooling plate. However, Storm teaches a cooling plate (col 6, ln 4-7, col 6, ln 18-19, col 6, ln 45-48, fig 1, 3, 4). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Storm because the cooling system prevents burns to a patient's skin.

Regarding claim 37, claim 36 is obvious as above. Knowlton further teaches wherein said antenna comprises: a plurality of antennas (para [0302]) and a distribution element arranged to transmit said energy to said plurality of antennas (para [0303]).

Regarding claim 38, claim 37 is obvious as above. Knowlton further teaches wherein said distribution element comprises a microwave switch (para [0223]).

Regarding claim 39, claim 37 is obvious as above. Knowlton further teaches wherein said distribution element comprises a power splitter (para [0222]).

Regarding claim 40, claim 36 is obvious as above. Knowlton does not specifically teach wherein said energy transmission further comprises: a plurality of scattering elements positioned between said apertures and said distal end of said applicator. However, Knowlton does teach the use of a dielectric material to create the housing, which includes the apertures (para [0162]). It would have been obvious to one of ordinary skill in the art that the dielectric elements serve the same function as the scattering elements.

Regarding claim 41, claim 36 is obvious as above. Storm further teaches wherein said cooling circuit further comprises a cooling chamber positioned between said antenna aperture and a proximal side of said cooling plate (col 6, ln 4-7, col 6, ln 18-19, col 6, ln 45-48, fig 1, 3, 4). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Storm because a cooling chamber between the antenna and the cooling plate allows for heat transfer from the antenna to the cooling plate in order to maintain the antenna at reasonable temperatures.

Regarding claim 42, Knowlton teaches an energy transmission applicator comprising:
a disposable interface at a distal end of said applicator, said disposable interface comprising a disposable engagement mechanism (para [0162]);

a waveguide assembly including a plurality of antenna apertures arranged to transmit energy through said distal end of said applicator (para [0302]-[0303]), a cooling circuit, wherein at least a portion of said cooling circuit is positioned between said antenna and said distal end of said applicator (para [0140]) but does not teach a cooling plate.

However, Storm teaches a cooling plate (col 6, ln 4-7, col 6, ln 18-19, col 6, ln 45-48, fig 1, 3, 4). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Storm because the cooling system prevents burns to a patient's skin.

Regarding claim 43, claim 42 is obvious as above. Knowlton further teaches wherein said waveguide assembly comprises:
a plurality of waveguide antennas positioned in an antenna cradle (para [0092], [0302]-[0303];
a distribution element arranged to transmit said energy to said plurality of antennas (para [0302]-[0303], fig 72).

Regarding claim 44, Claim 43 is obvious as above. Knowlton further teaches wherein said distribution element comprises a microwave switch (para [0233], [0313]).

Regarding claim 45, claim 43 is obvious as above. Knowlton further teaches wherein said distribution element comprises a power splitter (para [0222]).

Regarding claim 46, claim 42 is obvious as above. Knowlton does not specifically teach wherein said energy transmission further comprises: a plurality of scattering elements positioned between said apertures and said distal end of said applicator. However, Knowlton does teach the use of a dielectric material to create the housing, which includes the apertures (para [0162]). It would have been obvious to one of ordinary skill in the art that the dielectric elements serve the same function as the scattering elements.

Regarding claim 47, claim 42 is obvious as above. Storm further teaches wherein said cooling circuit further comprises cooling chambers positioned between said antenna apertures and a proximal side of said cooling plate (col 6, ln 4-7, col 6, ln 18-19, col 6, ln 45-48, fig 1, 3, 4). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Storm because a cooling chamber between the antenna and the cooling plate allows for heat transfer from the antenna to the cooling plate in order to maintain the antenna at reasonable temperatures.

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Regarding claim 48, claim 47 is obvious as above. Knowlton teaches wherein said waveguide assembly comprises: a plurality of waveguide antennas positioned in an antenna cradle (para [0092], [0302]-[0303]); a distribution element arranged to transmit said energy to said plurality of antennas (para [0302]-[0303], fig 72).

Regarding claim 49, claim 48 is obvious as above. Storm further teaches wherein said cooling circuit further comprises cooling passages in said antenna cradle, said cooling passages being connected to said cooling chambers (col 6, ln 4-7, col 6, ln 18-19, col 6, ln 45-48, fig 1, 3, 4). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Storm because a cooling chamber between the antenna and the cooling plate allows for heat transfer from the antenna to the cooling plate in order to maintain the antenna at reasonable temperatures.

Regarding claim 55, claim 42 is obvious as above. Storm teaches wherein said cooling plate comprises: a proximal surface and a distal surface (col 6, ln 4-7, col 6, ln 18-19, col 6, ln 45-48, fig 1, 3, 4), but does not teach one or more thermocouple grooves in said distal surface and one or more thermocouples positioned in said thermocouple grooves. However, Knowlton teaches the use of thermocouples to monitor temperature and positioning the thermocouples in a variety of places within the housing (para [0270]). It would have been obvious to one of ordinary skill in the art that the thermocouples could have been integrated into the cooling plate in order to monitor performance of the cooling plate when the device is in use and that Knowlton could be modified by the teachings of Storm because doing so provides a way to monitor device temperature and ensure safe use of the device.

Regarding claim 56, claim 55 is obvious as above. Neither Knowlton nor Storm teaches wherein said thermocouple grooves are arranged parallel to an E-Field emitted by said waveguide assembly when said transmitted energy is microwave energy. However, with routine experimentation, it would have been obvious to one of ordinary skill in the art that the electrical fields could be manipulated to run parallel to thermocouples to ensure proper performance of the thermocouples when the device transmitting microwave energy.

Regarding claim 57, claim 55 is obvious as above. Neither Knowlton nor Storm teach wherein said microwave energy is transmitted in a TE₁₀ mode. However, with routine experimentation, it would have been obvious to one of ordinary skill in the art that different modes of microwave operation could be used to achieve different results on a patient's skin.

Regarding claim 58, Knowlton teaches a method of cooling tissue using an energy transmission applicator comprising an antenna aperture (para [0092]), said method comprising the steps of: engaging tissue in said energy transmission applicator adjacent said cooling plate (para [0093]-[0094]); applying energy to said tissue (para [0281]), but does not teach a cooling plate, said cooling plate having a proximal surface and a distal surface and being positioned at a distal end of said energy transmission applicator and said antenna aperture being positioned in said energy transmission applicator proximal to said cooling plate, or a cooling plate or passing cooling fluid between said antenna aperture and a proximal surface of said cooling plate or applying energy through the cooling plate. However, Storm teaches a cooling plate, said cooling plate having a proximal surface and a distal surface and being positioned at a distal end of said energy transmission applicator and said antenna aperture being positioned in said energy transmission applicator proximal to said cooling plate (col 6, ln 4-7, col 6, ln 18-19, fig 1, 3, 4) and a cooling plate (col 6, ln 4-7, col 6, ln 18-19, fig 1, 3, 4) and passing cooling fluid between said antenna aperture and a proximal surface of said cooling plate (col 6, ln 45-48) and applying energy through the cooling plate (col 6, ln 4-7, col 6, ln 18-19, col 6, ln 45-48, fig 1, 3, 4). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Storm because a cooling chamber allows for heat transfer from the antenna to the cooling plate in order to maintain the antenna at reasonable temperatures to prevent burning the patient.

Claim 35 lacks an inventive step under PCT Article 33(3) as being obvious over Knowlton and Storm in light of Anderson.

Regarding claim 35, Claim 31 is obvious as above. Neither Knowlton nor Storm teach wherein said step of drawing air from an applicator chamber includes the step of drawing air through a bio-barrier. However, Anderson teaches wherein said step of drawing air from an applicator chamber includes the step of drawing air through a bio-barrier (para [0074], [0129]). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Anderson because doing so maintains the bio-barrier at a normalized pressure relative to prevent tearing or stretching of the bio-barrier due to the vacuum pressure

Claims 50-54 and 59 lack an inventive step under PCT Article 33(3) as being obvious over Knowlton and Storm in light of US 2004/0243200 A1 to Turner et al (hereinafter Turner).

Regarding claim 50, claim 42 is obvious as above. Knowlton teaches a plurality of waveguide antennas (para [0302]-[0303]); but does not teach a plurality of isolation elements positioned between said antennas. However, Turner teaches the use of microwave chokes to eliminate the transfer of magnetic fields to nearby wires (para [0040]). It would have been obvious to one of ordinary skill in the art that Knowlton and Storm could be modified by the teachings of Turner and that the isolation elements could be located at the ends because doing so eliminates specific frequencies and can protect nearby wires from magnetic fields.

Regarding claim 51, claim 50 is obvious as above. Neither Knowlton nor Storm teach wherein said waveguide assembly further comprises a first isolation element positioned at a first end of said waveguide assembly and a second isolation element positioned at a second end of said waveguide assembly. However, Turner teaches the use of microwave chokes to eliminate the transfer of magnetic fields to nearby wires (para [0040]). It would have been obvious to one of ordinary skill in the art that Knowlton and Storm could be modified by the teachings of Turner because doing so eliminates specific frequencies and can protect nearby wires from magnetic fields.

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Regarding claim 52, claim 51 is obvious as above. Knowlton teaches wherein said isolation elements comprise a shim of microwave absorption material (para [0162] . housing made of dielectric material).

Regarding claim 53, claim 51 is obvious as above. Neither Knowlton nor Storm teach wherein said isolation elements comprise a microwave choke. However, Turner teaches wherein said isolation elements comprise a microwave choke (para [0040]. It would have been obvious to one of ordinary skill in the art that Knowlton and Storm could be modified by the teachings of Turner because doing so eliminates specific frequencies and can protect nearby wires from magnetic fields.

Regarding claim 54, claim 50 is obvious as above. Knowlton teaches wherein said waveguide antenna comprises an inner dielectric (para [0162]);
an outer shell surrounding said inner dielectric on every side except said aperture (para [0162]).

Regarding claim 59, Knowlton teaches a method of distributing electromagnetic energy to tissue, said method comprising radiating energy from an antenna aperture (para [0281]);
radiating energy through cooling fluid wherein said cooling fluid flows through a cooling chamber beneath said aperture (para [0140]-[0141], [0281]), and radiating energy through a tissue bio-barrier (para [0281]) but does not teach radiating energy past scattering elements or radiating energy through a cooling plate. However, Turner teaches radiating energy past scattering elements (para [0040]). Additionally, Storm teaches radiating energy past cooling plate (col 6, ln 4-7, col 6, ln 18-19, col 6, ln 45-48, fig 1, 3, 4). It would have been obvious to one of ordinary skill in the art that Knowlton could be modified by the teachings of Turner and Storm because doing so provides a means to ensure that the microwaves do not emit in all directions and that the cooling plate provides a means to ensure that a patient's skin does not burn. It also would have been obvious to one of ordinary skill in the art that the various components could be positioned relative to one another to form a device that can be held by a doctor without undue experimentation.

Claims 1-7 and 9-59 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.